

## REMARKS

Reconsideration of this application is requested in view of the amendments to the claims and the remarks presented herein.

The claims in the application are claims 2 to 8 and 10 to 16, all other claims having been cancelled.

Claims 2 to 6, 8 and 10 to 16 were rejected under 35 USC 102 as being anticipated by the newly cited Killian reference and claim 7 was rejected as being obvious thereover. With respect to claim 15, the Examiner referred to Figure 5 of the reference as showing different standard operating procedures performed in conjunction with the testing of blood and Figure 5 involves the validation of a lot of reagents used in blood testing and Figure 5 allegedly shows the user following a series of sequential validation steps to validate a single lot of reagents used therein and that the steps of Figure 5 are sequential in the sense that they must be followed in an exact order and are conditional in the sense that the subsequent steps are not reached until previous steps are completed and that any of the information in Fig. 5 could be read as post-injection information since the information may be entered at any time such as after a previously approved lot of blood samples had been approved, the blood associated with those samples had been reinjected. The Examiner deemed that the inventions would be obvious therefrom.

Applicants respectfully traverse these grounds of rejection since the Killian reference does not anticipate or render obvious Applicants' invention as presently claimed. Since the Killian reference is a newly cited reference in the final rejection, it is deemed that entry of the amendment is proper since that is the first attempt Applicants have had to consider the same. Claims 15 and 16 have been amended to recite the screen page being closed responsibly to a closing order only if all of the instructions have been carried out and this is supported by lines 24 to 32 of page 10. The claims have also been amended to incorporate an alarm icon being provided for prompting an operator to consult a screen page listing anomalies detected during the processing stage and this is supported by lines 3 to 5 of page 12. These features are not in the Killian reference.

The Killian reference discloses a system for automatically testing biological fluids including a network database holding test protocols and test results for identified samples. The system implements a method for processing information related to blood samples within a biology testing system but not within a therapeutic process. Moreover, the biological testing system of Killian is not related to a therapeutic process involving a reinjection operation into a patient from whom cells have been collected. The routine for recording master lot information disclosed in lines 20 to 29 of page 25 and lines 1 to 20 of page 26 and illustrated in Figure 5 of the reference includes a succession of steps such as selection data entering and conformation request stages and cannot be assimilated to a standard operating procedure for preparation comprising a series of functional stages.

Moreover, each stage of the routine illustrated by Figure 5 of the reference is not followed by a stage of sequential and conditional validation of the said stage. Therefore, Killian differs from the subject of claim 15 in that it does not relate to a method for processing information used for quality management in a therapeutic process involving several entities optionally remote including an operational entity and a preparation laboratory. It further does not disclose after each functional stage a stage of sequential and conditional validation of the said functional stage with each screen page being closed responsive to a closing order only if all of the operational instructions within the screen page have been carried. It further does not disclose an alarm icon being provided for prompting an operator to consult a screen page listing anomalies detected during the said processing stage and also does not disclose a stage for inputting post-reinjection follow up information and forwarding the said information to said operational entity. Therefore, Killian does not anticipate the subject matter of claims 15 and 16.

With respect to any obviousness type rejection, Killian also does not render obvious Applicants' invention. The system disclosed by Killian is intended to process control for fluid biological testing and not for quality management in a therapeutic process since the Killian system does not include any reinjection stage and is not intended to control a therapeutic process. In fact, Killian is concerned with testing blood samples which is well known to include some destructive treatments applied on a small part of each sample, said tested part being disposed of once the testing is finished. In contrast

thereto, the present invention applies to a modifying treatment applied to the right same cells that will be reinjected into the patient as indicated in line 20 of page 1. It is therefore clear that Killian has objective which totally contradicts the subject matter of Applicants' invention.

Moreover, as illustrated in Figure 5 and quoted by the Examiner, "Some of the steps are also conditional in the sense that they require that "if-then" steps. Steps 74 and 84 are conditional of the steps which involve "if-then" decisions. Indeed, in Killian, these conditional steps 74 and 84 are not blocking steps as in Applicants' invention since the said steps will lead either to step 76, 86 or to steps 84, 78. Therefore, these step features disclosed by Killian totally contradict the subject matter of amended claim 15 as they do not result in the interruption of the process when operational instructions are not carried out. Killian would not teach or suggest to one skilled in the art of quality management in therapeutic processes, the principle of a stage of sequential and conditional validation after each functional stage, the completion of which being a strict condition to the passing from said functional stage to the following stage within a method and system as recited in claim 15. Therefore, Killian does not render obvious the invention. Therefore, withdrawal of these grounds of rejection is requested.

In view of the amendments to the claims and the above remarks, it is believed that the claims clearly point out Applicants' patentable contribution and favorable reconsideration of the application is requested.

Respectfully submitted,  
Muserlian, Lucas and Mercanti



---

Charles A. Muserlian, 19,683  
Attorney for Applicants  
Tel. # (212) 661-8000

CAM:ds  
Enclosure